

46851-10

11/6/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

NOV 6 2013

Edward Cassinis  
Certol International  
6120 East 58<sup>th</sup> Avenue  
Commerce City, CO 80022

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Subject: ProSpray<sup>TM</sup> wipes  
EPA Registration No.: 46851-10  
Application Date: 08/13/2013  
Receipt Date: 08/14/2013

Dear Mr. Cassinis:

This acknowledges the receipt of your notification, submitted under the provision of PR Notice 98-10 and FIFRA section 3(c)9.

**Proposed Notification**

- Addition of alternative package opening instructions
- Optional marketing claim, "Fresh Scent"
- Revised Storage and Disposal language

**General Comments**

Based on a review of the submitted materials, your notification for the additional instructions, optional marketing claim, and revised Storage and Disposal language, is acceptable. This has been made a part of your file.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at [campbell.jacqueline@epa.gov](mailto:campbell.jacqueline@epa.gov) or Jaclyn Pyne by telephone at (703) 347-0213 or by e-mail at [pyne.jaclyn@epa.gov](mailto:pyne.jaclyn@epa.gov). When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Campbell".

Jacqueline Campbell  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

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**ProSpray™ wipes**  
Disinfectant Towelettes

Tuberculocidal, Virucidal\*, Bactericidal, Fungicidal

\_\_\_\_\_ Pre-moistened Towelettes  
\_\_\_\_\_ x \_\_\_\_\_ in. ( \_\_\_\_\_ x \_\_\_\_\_ cm)  
Reorder No: \_\_\_\_\_  
Net Contents: \_\_\_\_\_ lbs. \_\_\_\_\_ oz.

Active Ingredients	
o-phenylphenol . . . . .	0.28%
o-benzyl-p-chlorophenol . . . . .	0.03%
Inert Ingredients . . . . .	99.69%
Total . . . . .	100.00%

**NOTIFICATION**  
Date Reviewed: 11/6/13  
Reviewed By: JP

E.P.A. Reg. No. 46851-10  
E.P.A. Est. No. 75586-NJ-001

Keep Out of Reach of Children  
(\*Caution SYMBOL) **CAUTION**

NOT A BABY WIPE (\*ICON)

PRODUCT BARCODE: +H816 \_\_\_\_\_

**FIRST AID:**

*If swallowed:* Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by poison control center or doctor. Do not give anything by mouth to an unconscious person.  
*If inhaled:* Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further treatment advice.  
*If in eyes:* Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a Poison Control Center or doctor for treatment advice.

**HOTLINE NUMBER:** In case of emergency, call toll free 1-800-535-5053. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

**PRECAUTIONARY STATEMENT**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed. Wash thoroughly with soap and water before eating, drinking, chewing gum or using tobacco. Harmful if inhaled. Avoid breathing vapors.

## A BISYNTHETIC PHENOL SOLUTION IMPREGNATED IN A UNIFORM RELEASE TOWELETTE

ProSpray wipes Disinfectant Towelettes are intended for use in hospitals, medical, dental and veterinary offices, laboratories, industrial clean rooms, nursing homes, ambulances, police vehicles, hotels, schools, homes, health spas, grocery stores, shopping centers, boats, autos, and toilet seats. Use on inanimate surfaces and equipment such as stainless steel, formica, glass tables, carts, baskets, counters, cabinets, telephones, grocery cart handles, grocery cart child seats, shopping cart handles, shopping cart child seats, and other hard non-porous surfaces.

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### DIRECTIONS FOR USE:

**IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. READ ENTIRE LABEL BEFORE USING THIS PRODUCT.**

**DO NOT USE AS A BABY WIPE. Must not be used in hospital nurseries.**

**To Open Package:** Open cap lid and pull up firmly on lid to remove the entire cap from the canister. Remove protective seal. Locate wipe at the center of the roll and insert corner of wipe through opening in lid. Replace lid. Pull sheet up and slightly to the side. The next wipe pops up automatically. Always snap lid securely shut between uses to prevent moisture loss.

*Alternative Package Opening Instructions:*

**Preparation of Dispenser:** *Lift up tab and pull back to expose the entire opening. Do not remove Peel & Seal tab. Grasp exposed edge of towelette and pull out. Close Peel & Seal tab to prevent evaporation by returning it to its original position and press down firmly.*

Remove one ProSpray wipes Disinfectant Towelette, unfold, wipe surface to remove excess organic debris and thoroughly clean surface. Use a second towelette to thoroughly wet surface. Ensure surface remains wet for 10 minutes to destroy or inactivate bacteria including: Escherichia Coli 0113, Staphylococcus aureus, Salmonella typhosa, Pseudomonas aeruginosa, Mycobacterium tuberculosis var.bovis; fungi including: Trichophyton mentagrophytes, and the following viruses\*: Herpes simplex virus types 1 & 2, Vaccinia virus, Influenza virus type A 1 (New Jersey), Influenza B (Maryland), and HIV-1 (AIDS virus). Use on non-food contact surfaces only. When using in grocery stores or shopping centers and similar locations: wipe thoroughly in order to clean non-food contact surfaces on carts, such as grocery cart handles and grocery cart child seats.

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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**KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other setting in which there is an expected likelihood of soiling inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear disposable latex gloves, gowns, masks, and eye coverings.

**CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**CONTACT TIME:** Leave surface wet for 2 minutes. Use a 10 minute contact time for disinfection against all other virus, bacteria, and fungi claimed.

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**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store at room temperature.

**PESTICIDE DISPOSAL:** Do not reuse towelettes. Dispose of used towelette and empty container in regular trash. To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

**CONTAINER STORAGE/DISPOSAL:** Store in an area inaccessible to children. Wipes: Dispose of (wipe) (towelette) in trash after use. Do not flush. Canister: Tightly close lid between uses to retain moisture. Nonrefillable container. Do not reuse or refill this (container) (canister). Offer empty (container) (canister) for recycling if available or discard in trash.

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Optional Marketing Claims:

Lemon Scent.

Fresh Scent.

Kills Pandemic 2009 H1N1 Influenza A Virus.

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